



PATENT  
Attorney Docket No. 1007  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Gillies *et al.* CONFIRMATION NO.: 3473  
SERIAL NO.: 09/621,268 GROUP NO.: 1642  
FILING DATE: July 21, 2000 EXAMINER: K. Canella, Ph.D.  
TITLE: Fc Fusion Proteins for Enhancing the Immunogenicity of Protein and Peptide Antigens

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

**REMARKS**

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☐ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☒ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☒ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or

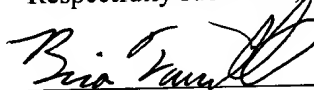
- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

Date: September 19, 2003  
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Tel. No.: (617) 248-7697  
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2682107

Respectfully submitted,



\_\_\_\_\_  
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FORM PTO - 1449

## INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: LEX-007

APPLICANT(S): Gillies et al.

SERIAL NO.: 09/621,268 CONF. NO.: 3473

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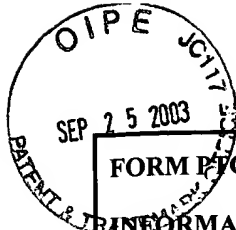
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## U.S. PATENT DOCUMENTS

EXAM INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A8	07/348,237	5/5/89	Rosenblum et al.			
	A9	4,196,265	4/1/80	Koprowski et al.			
	A10	4,469,797	9/4/84	Albarella			
	A11	4,676,980	6/30/87	Segal et al.			
	A12	4,816,567	3/28/89	Cabilly et al.			
	A13	4,946,778	8/7/90	Ladner et al.			
	A14	5,019,368	5/28/91	Epstein et al.			
	A15	5,073,627	12/17/91	Curtis et al.			
	A16	5,114,711	5/19/92	Bell et al.			
	A17	5,116,964	5/26/92	Capon et al.			
	A18	5,199,942	4/6/93	Gillis			
	A19	5,225,538	7/6/93	Capon et al.			
	A20	5,225,539	7/6/93	Winter			
	A21	5,258,498	11/2/93	Huston et al..			
	A22	5,314,995	5/24/94	Fell, Jr. et al.			
	A23	5,359,035	10/25/94	Habermann			
	A24	5,514,582	5/7/96	Capon et al.			
	A25	5,541,087	7/30/96	Lo et al.			
	A26	5,543,297	8/6/96	Cromlish, et al.			
	A27	5,552,524	09/03/96	Basinski et al.			
	A28	5,585,089	12/17/96	Queen et al.			
	A29	5,609,846	3/11/97	Goldenberg			
	A30	5,624,821	4/29/97	Winter et al.			
	A31	5,639,725	6/17/97	O'Reilly et al.			
	A32	5,645,835	7/8/97	Fell, Jr. et al.			
	A33	5,650,150	7/22/97	Gillies			

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## INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: LEX-007

APPLICANT(S): Gillies et al.

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## U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A34	5,650,492	7/22/97	Gately et al.			
	A35	5,667,776	9/16/97	Zimmerman et al.			
	A36	5,679,543	10/21/97	Lawlis			
	A37	5,691,309	11/25/97	Basinski et al.			
	A38	5,719,266	02/17/98	DiMarchi et al.			
	A39	5,723,125	3/3/98	Chang et al.			
	A40	5,726,044	3/10/98	Lo et al.			
	A41	5,733,876	3/31/98	O'Reilly et al.			
	A42	5,756,461	05/26/98	Stephens			
	A43	5,770,195	6/23/98	Hudziak et al.			
	A44	5,807,715	9/15/98	Morrison et al.			
	A45	5,837,682	11/17/98	Folkman et al.			
	A46	5,843,423	12/1/98	Lyman et al.			
	A47	5,854,205	12/29/98	O'Reilly et al.			
	A48	5,858,347	1/12/99	Bauer et al.			
	A49	5,885,795	3/23/99	O'Reilly et al.			
	A50	5,886,178	3/23/99	Allen et al.			
	A51	5,888,772	3/30/99	Okasinski et al.			
	A52	5,908,626	6/1/99	Chang et al.			
	A53	5,922,685	7/13/99	Rakhmilevich et al.			
	A54	6,100,387	8/8/00	Herrmann et al.			
	A55	6,169,070 B1	1/2/01	Chen et al.			
	A56	6,171,588 B1	1/9/01	Carron et al.			
	A57	6,348,192 B1	2/19/02	Chan et al.			
	A58	6,444,792 B1	9/3/02	Gray et al.			
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## INFORMATION DISCLOSURE STATEMENT

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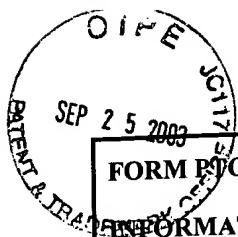
APPLICANT(S): Gillies et al.

SERIAL NO.: 09/621,268 CONF. NO.: 347

FILING DATE: July 21, 2000 GROUP: 1642

## FOREIGN PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTR Y CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B4	0 158 198 A1	10/16/85	EP					Y
	B5	0 211 769 A2	2/25/87	EP					Y
	B6	0 256 714 A2	2/24/88	EP					Y
	B7	0 294 703 A2	12/14/88	EP					Y
	B8	0 308 936 B1	3/29/89	EP					Y
	B9	0 314 317 B1	5/3/89	EP					Y
	B10	0 318 554 B1	6/7/89	EP					Y
	B11	0 319 012 A2	6/7/89	EP					Y
	B12	0 326 120 B1	8/2/89	EP					Y
	B13	0 350 230 A2	1/10/90	EP					Y
	B14	0 375 562 B1	6/27/90	EP					Y
	B15	0 396 387 A2	11/7/90	EP					Y
	B16	0 439 095 A2	7/31/91	EP					Y
	B17	0 511 747 A1	11/4/92	EP					Y
	B18	0 601 043 B1	6/15/94	EP					Y
	B19	0 640 619 A1	3/1/95	EP					Y
	B20	0 668 353 A1	8/23/95	EP					Y
	B21	0 706 799 A2	4/17/96	EP					Y
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	B24	93100115.3	7/14/93	CN					N
	B25	93100115.3	7/14/93	CN				Y	Y
	B26	37 12985 A1	11/3/88	DE					N
	B27	37 12985	11/2/88	DE				Y	Y
	B28	2 292 382 A	2/21/96	GB					Y
	B29	63-267278	11/4/88	JP					N
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## INFORMATION DISCLOSURE STATEMENT

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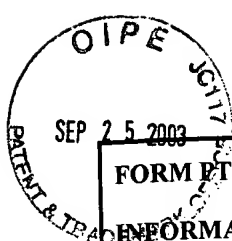
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FILING DATE: July 21, 2000 GROUP: 1642

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EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B31	63-267296	11/4/88	JP					N
	B32	63-267296	11/4/88	JP				Y	Y
	B33	0 237 019 A2	9/16/87	EP				English counterpart of JP 63-267296	Y
	B34	WO 86/01533	3/13/86	PCT					Y
	B35	WO 88/00052	1/14/88	PCT					Y
	B36	WO 88/09344	12/1/88	PCT					Y
	B37	WO 89/02922	4/6/89	PCT					Y
	B38	WO 89/09620	10/19/89	PCT				Abstract in English	N
	B39	WO 90/03801	4/19/90	PCT					Y
	B40	WO 91/00360	1/10/91	PCT					Y
	B41	WO 91/04329	04/04/91	PCT					Y
	B42	WO 91/08298	6/13/91	PCT					Y
	B43	WO 91/13166	9/5/91	PCT					Y
	B44	WO 91/14438	10/3/91	PCT					Y
	B45	WO 92/02240	2/20/92	PCT					Y
	B46	WO 92/08495	5/29/92	PCT					Y
	B47	WO 92/08801	5/29/92	PCT					Y
	B48	WO 92/16562	10/1/92	PCT					Y
	B49	WO 93/03157	2/18/93	PCT					Y
	B50	WO 93/10229	5/27/93	PCT					Y
	B51	WO 94/24160	10/27/94	PCT					Y
	B52	WO 94/25055	11/10/94	PCT					Y
	B53	WO 95/05468	2/23/95	PCT					Y
	B54	WO 95/21258	8/10/95	PCT					Y
	B55	WO 95/28427	10/26/95	PCT					Y
	B56	WO 96/04388	02/15/96	PCT					Y
	B57	WO 96/05309	2/22/96	PCT					Y
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## INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: LEX-007

APPLICANT(S): Gillies et al.

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## FOREIGN PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B58	WO 96/18412	6/20/96	PCT					Y
	B59	WO 96/31526	10/10/96	PCT					Y
	B60	WO 97/00317	1/3/97	PCT					Y
	B61	WO 97/00319	1/3/97	PCT					Y
	B62	WO 97/15666	5/1/97	PCT					Y
	B63	WO 97/20062	6/5/97	PCT					Y
	B64	WO 97/24440	7/10/97	PCT					Y
	B65	WO 97/26335	7/24/97	PCT					Y
	B66	WO 97/30089	8/21/97	PCT					Y
	B67	WO 97/33617	9/18/97	PCT					Y
	B68	WO 97/33619	9/18/97	PCT					Y
	B69	WO 97/34631	9/25/97	PCT					Y
	B70	WO 97/43316	11/20/97	PCT					Y
	B71	WO 98/00127	1/8/98	PCT					Y
	B72	WO 98/06752	2/19/98	PCT					Y
	B73	WO 98/28427	7/2/98	PCT					Y
	B74	WO 98/46257	10/22/98	PCT					Y
	B75	WO 98/59244	12/30/98	PCT					Y
	B76	WO 99/02709	01/21/99	PCT					Y
	B77	WO 99/03887	01/28/99	PCT					Y
	B78	WO 99/29732	6/17/99	PCT					Y
	B79	WO 99/43713	9/2/99	PCT					Y
	B80	WO 99/52562	10/21/99	PCT					Y
	B81	WO 99/53958	10/28/99	PCT					Y
	B82	WO 99/60128	11/25/99	PCT					Y
	B83	WO 99/62944	12/09/99	PCT					Y

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## INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: LEX-007

APPLICANT(S): Gillies et al.

SERIAL NO.: 09/621,268 CONF. NO.: 3

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## FOREIGN PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B84	WO 99/66054	12/23/99	PCT					Y
	B85	WO 00/11033	3/2/00	PCT					Y
	B86	WO 00/34317	06/15/00	PCT					Y
	B87	WO 00/40615	7/13/00	PCT					Y
	B88	WO 00/68376	11/16/00	PCT					Y
	B89	WO 00/69913	11/23/00	PCT					Y
	B90	WO 00/78334 A1	12/28/00	PCT					Y
	B91	WO 01/07081 A1	2/1/01	PCT					Y
	B92	WO 01/10912 A1	2/15/01	PCT					Y
	B93	WO 03/015697 A2	2/27/03	PCT					Y

EXAM. INIT.

## OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)

C3	Abaza et al., (1992), "Effects of Amino Acid Substitutions Outside an Antigenic Site on Protein Binding to Monoclonal Antibodies of Predetermined Specificity Obtained by Peptide Immunization," <u>Journal of Protein Chemistry</u> , 11:5:433-444.
C4	Abstract XP-002116766, (1996), "Prostaglandins, their inhibitors and cancer," <u>Prostaglandins, Leukotrienes and Essential Fatty Acids</u> , 54:2:83-94.
C5	Afonso et al., (1994), "The Adjuvant Effect of Interleukin-12 in a Vaccine Against Leishmania Major," <u>Science</u> , 263:235-237.
C6	Arenberg et al. (1996), "Interferon- $\gamma$ -inducible Protein 10 (IP-10) Is an Angiostatic Factor That Inhibits Human Non-small Cell Lung Cancer (NSCLC) Tumorigenesis and Spontaneous Metastases," <u>J. Exp. Med.</u> , 184:981-992.
C7	Bacha et al., (1988), "Interleukin 2 Receptor-Targeted Cytotoxicity Interleukin 2 Receptor-mediated Action of a Diphtheria Toxin-related Interleukin 2 Fusion Protein," <u>J. Experimental Medicine</u> , 167:612-622
C8	Bachelot et al., (March 1998), "Retrovirus-Mediated Gene Transfer of an Angiostatin-Endostatin Fusion protein with Enhanced Anti-Tumor Properties In Vivo," <u>Proceedings of the Annual Meeting of the American Association for Cancer Research</u> , 39:271, Abstract #1856.
C9	Barnett et al., (1994), "Purification, characterization and selective inhibition of human prostaglandin G/H synthase 1 and 2 expressed in the baculovirus system," <u>Biochimica et Biophysica Acta</u> , 1209:130-139.
C10	Baselga, et al., (1998), "Recombinant Humanized Anti-HER2 Antibody (Herceptin <sup>TM</sup> ) Enhances the Antitumor activity of Paclitaxel and Doxorubicin against HER3/ <i>neu</i> Overexpressing Human Breast Cancer Xenografts," <u>Cancer Research</u> , 58:2825-2831.

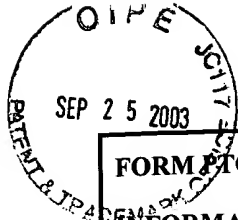
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## OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)

C11	Batova et al., (1999), "The Ch 14.18-GM-CSF Fusion Protein Is Effective at Mediating Antibody-dependent Cellular Cytotoxicity and Complement-dependent Cytotoxicity in Vitro," <u>Clinical Cancer Research</u> , 5:4259-4263.
C12	Batra et al., (1993), "Insertion of Constant Region Domains of Human IgG1 into CD4-PE40 Increases Its Plasma Half-Life," <u>Mol. Immunol.</u> , 30:379-386.
C13	Becker et al., (1996), "An Antibody-Interleukin 2 Fusion Protein Overcomes Tumor Heterogeneity by Induction of a Cellular Immune Response," <u>Proc. Natl. Acad. Sci.</u> , 93:7826-7831.
C14	Becker et al., (1996), "Eradication of human hepatic and pulmonary melanoma metastases in SCID mice by antibody-interleukin 2 fusion proteins," <u>Proc. Natl. Acad. Sci. USA</u> , 93:2702-2707.
C15	Beutler et al., (1988), "Tumor Necrosis, Cachexia, Shock, and Inflammation: A Common Mediator," <u>Ann. Rev. Biochem.</u> , 57:505-518.
C16	Bissery et al., (1997), "The Taxoids," in <u>Cancer Therapeutics: Experimental and Clinical Agents</u> , Teicher, ed., 175-193.
C17	Bjorn et al., (1985), "Evaluation of Monoclonal Antibodies for the Development of Breast Cancer Immunotoxins," <u>Cancer Research</u> , 45:1214-1221.
C18	Boehm et al., (1997), "Antiangiogenic therapy of experimental cancer does not induce acquired drug resistance," <u>Nature</u> , 390:404-407.
C19	Boehm et al., (1998), "Zinc-Binding of Endostatin Is Essential for Its Antiangiogenic Activity," <u>Biochemical and Biophysical Research Communications</u> , 252:190-194.
C20	Brooks et al., (1994), "Integrin $\alpha_v\beta_3$ Antagonists Promote Tumor Regression by Inducing Apoptosis of Angiogenic Blood Vessels," <u>Cell</u> , 79:1157-1164.
C21	Buchli et al., (1993), "Structural and Biologic Properties of a Human Aspartic Acid-126 Interleukin-2 Analog," <u>Archives of Biochemistry and Biophysics</u> , 307:2:411-415.
C22	Burgess et al., (1990), "Possible Dissociation of the Heparin-binding and Mitogenic Activities of Heparin-binding (Acidic Fibroblast) Growth Factor-1 from Its Receptor-binding Activities by Site-directed Mutagenesis of a Single Lysine Residue," <u>Journal of Cell Biology</u> , 111:2129-2138.
C23	Canfield et al., (1991), "The Binding Affinity of Human IgG for its High Affinity Fc Receptor is Determined by Multiple Amino Acids in the CH2 Domain and Is Modulated by the Hinge Region," <u>Journal of Experimental Medicine</u> , 173:6:1483-1491.
C24	Cao et al., (1996), "Kringle Domains of Human Angiostatin," <u>The Journal of Biological Chemistry</u> , 271:46:29461-29467.
C25	Cao et al., (1997), "Kringle 5 of Plasminogen is a Novel Inhibitor of Endothelial Cell Growth," <u>The Journal of Biological Chemistry</u> , 272:36:22924-22928.

EXAMINER

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INFORMATION DISCLOSURE STATEMENT		APPLICANT(S): Gillies et al.
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		FILING DATE: July 21, 2000 GROUP: 1642
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	C26	Capon et al., (1989), "Designing CD4 immunoadhesins for AIDS therapy," <u>Nature</u> , 337:525-531.
	C27	Caton et al., (1986), "Structural and functional implications of a restricted antibody response to a defined antigenic region on the influenza virus hemagglutinin," <u>The EMBO Journal</u> , 5:7:1577-1587.
	C28	Chan et al., (1991), "Induction of Interferon $\gamma$ Production by Natural Killer Cell Stimulatory Factor: Characterization of the Responder Cells and Synergy with Other Inducers," <u>J. Exp. Med.</u> , pp. 869-879.
	C29	Chang et al., (1989), "Overview of Interleukin-2 as an Immunotherapeutic Agent," <u>Seminars in Surgical Oncology</u> , 5:385-390.
	C30	Chang et al., (1996), "A Point Mutation in Interleukin-2 that Alters Ligand Internalization," <u>Journal of Biological Chemistry</u> , 271:23:13349-13355.
	C31	Chaudhary et al., (1988), "Selective killing of HIV-infected cells by recombinant human CD4-Pseudomonas exotoxin hybrid protein," <u>Nature</u> , 335:370-372.
	C32	Chaudhary et al., (1989), "A recombinant immunotoxin consisting of two antibody variable domains fused to Pseudomonas exotoxin," <u>Nature</u> , 339:394-397.
	C33	Chen et al., (1997), "Eradication of Murine Bladder Carcinoma by Intratumor Injection of a Bicistronic Adenoviral Vector Carrying cDNAs for the IL-12 Heterodimer and Its Inhibition by the IL-12 p40 Subunit Homodimer," <u>Journal of Immunology</u> , 159:1:351-358.
	C34	Cheon et al., (1994), "High-affinity binding sites for related fibroblast growth factor ligands reside within different receptor immunoglobulin-like domains," <u>Proc. Natl. Acad. Sci. USA</u> , 91: 989-993.
	C35	Chuang et al., (1993), "Effect of new investigational drug taxol on oncolytic activity and stimulation of human lymphocytes," <u>Gynecol. Oncol.</u> , 49:291-298.
	C36	Cohen, S. L. et al., (1996), "Human leptin characterization," <u>Nature</u> , 382:589.
	C37	Cole et al., (1997), "Human IgG2 Variants of Chimeric Anti-CD3 Are Nonmitogenic to T Cells," <u>Journal of Immunology</u> , 159:3613-3621.
	C38	Collins et al., (1988), "Identification of Specific Residues of Human Interleukin 2 that Affect Binding to the 70-kDa Subunit (p70) of the Interleukin 2 Receptor," <u>Proc. Natl. Acad. Sci.</u> , 85:7709-7713.
	C39	Colombo et al., (1996), "Amount of Interleukin 12 Available at the Tumor Site is Critical for Tumor Regression," <u>Cancer Research</u> , 56:2531-2534.
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APPLICANT(S): Gillies et al.

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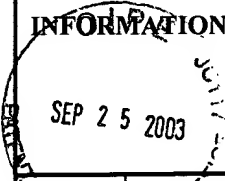
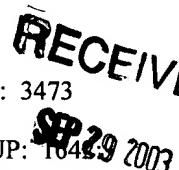

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SEP 25 2003		SERIAL NO.: 09/621,268 CONF. NO.: 3473
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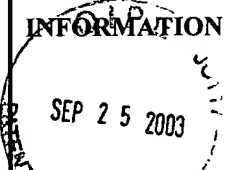
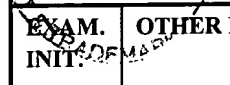

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EXAMINER

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<b>FORM PTO - 1449</b> <b>INFORMATION DISCLOSURE STATEMENT</b> 		ATTORNEY DOCKET NO.: LEX-007 APPLICANT(S): Gillies et al. SERIAL NO.: 09/621,268    CONF. NO.: 3473 FILING DATE: July 21, 2000    GROUP: 1642	
<b>EXAM. INIT.</b> 	<b>OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)</b> 		
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